DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

OK BIOTECH CO., LTD.
KE-MIN JEN
OFFICIAL CORRESPONDENT
NO. 91, SEC. 2, GONGDAOWU 5TH ROAD
HSINCHU CITY 30070, CHINA (TAIWAN)

April 15, 2015

Re: K141914
Trade/Device Name: Prodigy® Autocode Eject TM Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: March 1, 2015
Received: March 11, 2015

Dear Ke-min Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Stayce Beck -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141914

Device Name
PRODIGY® AutoCode Eject TM Blood Glucose Monitoring System

Indications for Use *(Describe)*
Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes, or for neonatal use. The alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).
PRODIGY® No Coding Test Strips are intended for use with the PRODIGY® AutoCode® Eject blood glucose meter to measure the concentration of the blood glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh for self-testing at home. They are for testing outside the body (in vitro diagnostic use only) . Do not use them for diagnosis of, or screening for diabetes or for testing on neonates. PRODIGY® No Coding Test Strips are used as an aid to monitor the effectiveness of diabetes control.
This system contains a speaking function, but is not intended for use by the visually impaired.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

5. 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

Type Of 510(K) Submission	Traditional
Basis for the submission	A New Device
Common Name Of The Proposed Device	Blood Glucose Monitoring System
Trade name	*PRODIGY AutoCode Eject™ Blood Glucose Monitoring System*
510(K) Submitter	OK BIOTECH CO., LTD. No. 91, Sec. 2, Gongdao 5th Road, 30070, Hsinchu City, Taiwan Telephone: +886-3-516-0258 Fax:+886-3-516-0028 Email: service@okbiotech.com
Owner Number	9090860
Date prepared	April 14, 2015
Official Correspondent	Dr. JEN, KE-MIN TEL: 886-3-5208829 FAX: 886-3-5209783 Email: ceirs.jen@msa.hinet.net
Preference For Continued Confidentiality (21 CFR 807.95)	510(k) Summary
Classification Regulation	SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER (21 CFR 862.1345)
Class	II
Panel	Clinical Chemistry
Product Code	NBW
Predicate Device	*PRODIGY Preferred® Blood Glucose Monitoring System* **(K122338)**

- **Intended Use:**

Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System should not be used for the diagnosis of,

or screening for diabetes, or for neonatal use. The alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

PRODIGY® No Coding Test Strips are intended for use with the PRODIGY® AutoCode® Eject blood glucose meter to measure concentration the of blood glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh for self-testing at home. They are for testing outside the body (in vitro diagnostic use only) . Do not use them for diagnosis of, or screening for diabetes or for testing on neonates. PRODIGY® No Coding Test Strips are used as an aid to monitor the effectiveness of diabetes control.

This system contains a speaking function, but is not intended for use by the visually impaired.

- **Device Description:**

The Prodigy® AutoCode® Eject Blood Glucose Monitoring System consists of a meter and Prodigy No Coding Test Strips. The system utilizes an electrochemical method-based meter and dry reagent biosensor (test strips) for blood glucose testing. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measurement of glucose in fresh whole blood and control solutions.

The Prodigy® AutoCode® Eject Blood Glucose Monitoring System is marketed as a meter only with a carrying case, batteries, Owner's Manual, Quick Reference Guide, Logbook, and Warranty Card.

The Prodigy® AutoCode® Eject Blood Glucose Monitoring System is also marketed as a meter kit with a carrying case, batteries, Owner's Manual, Quick Reference Guide, Logbook, and Warranty Card, Prodigy Lancing Device, Prodigy Lancets, Prodigy No Coding Test Strips, and Control Solution.

The Prodigy No Coding Test Strips utilizes the active enzyme is Glucose Oxidase, derived from Aspergillus niger. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System has a speaking function.

- **Test Principle**

The Blood glucose test is based on the measurement of electrical current generated by the reaction of capillary whole blood glucose with glucose oxidase on the test strip. The meter measures the strength of the current which is proportional to the concentration of glucose present and displays the corresponding blood glucose level.

- **Comparison Table**

Comparison Items	Subject device	Predicate device
MANUFACTURER	OK Biotech Co., Ltd.	Prodigy Diabetes Care, LLC
BRAND NAME	Prodigy	Prodigy
Model Number	AutoCode Eject™	Preferred®
Trade Name	Prodigy® AutoCode Eject™ Blood Glucose Monitoring System	Prodigy Preferred® Blood Glucose Monitoring System
Product Code	NBW	NBW
510K NO	K141914	K122338
Similarities		
Indications for use	Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The	The Prodigy Preferred Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The Prodigy Preferred

	Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Prodigy® AutoCode® Eject Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes, or for neonatal use. The alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). PRODIGY® No Coding Test Strips are intended for use with the PRODIGY® AutoCode® Eject blood glucose meter to measure concentration the of blood glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh for self-testing at home. They are for testing outside the body (in vitro diagnostic use only) . Do not use them for diagnosis of, or screening for diabetes or for testing on neonates. PRODIGY® No Coding Test Strips are used as an aid to monitor the effectiveness of diabetes control. This system contains a speaking function, but is not intended for use by the visually impaired.	Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Prodigy Preferred Blond Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Prodigy Preferred Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady -state times (when glucose is not changing rapidly).
Test Principle	The test is based on the measurement of electrical	Same

	current generated by the reaction of capillary whole blood glucose with glucose oxidase on the test strip. The meter measures the strength of the current which is proportional to the concentration of glucose present and displays the corresponding blood glucose level.	
Enzyme	Glucose oxidase	Same
Specimen Type	Capillary whole blood from fingertip and alternative sites (palm, forearm, upper-arm, calf and thigh)	Same
Test Strip	PRODIGY® No-Coding Test Strips	Same
Control solution	PRODIGY® Control Solution (Level 1 & Level 2)	Same
Sample Volume	0.7 μL	Same
Operating Temperature	50 °F - 104 °F 10~85% R. H.	Same
Strip Storage Temperature	39.2 - 104 °F 10~85% R. H.	Same
HCT Range	20 ~ 60 %	Same
Detecting range	20~600 mg/dL	same
code-checking mechanism	Code number checking	Same
temperature compensation mechanism	Automatic compensation with built-in thermistor	Same
Differences		
Measuring Time	6 seconds	7 seconds
Meter size	100 mm (L) × 56 mm (W) × 23	71 mm (L) × 60 mm (W) × 19

	mm (H)	mm (H)
Meter Weight	Approximate 79 g (w/ battery)	Approximate 45 g (w/battery)
Power Battery	1.5V AAA Alkaline battery x2	One 3V CR2032 battery
Memory Storage	450 tests	120 tests
Speaking feature	Yes	No

- **Substantial Equivalence (SE) Discussion**

  A claim of substantial equivalence is made to *PRODIGY Preferred® Blood Glucose Monitoring System (K122338)***.** Both of them have the same indications for use, the same working principle and technologies including using the same Prodigy No-Coding test strips and PRODIGY Control Solution, sample volume, operating & storage conditions, HCT range, detecting range.

  The major differences for the two devices are measuring time, meter dimensions, meter weight; power battery, memory storage, and speaking feature The speaking function for the subject device is indicated not to be used by visually impaired person, just an aid for all of the users. The subject device and predicate device are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. Thus the differences are due to the feature design aspects, not related to the safety or effectiveness aspects. They are substantially equivalent.

- **Synopsis of Test Methods and Results**

  Pre-clinical and clinical data are employed upon submission of this 510(K) premarket notification according to the *Guidance Document for In Vitro Diagnostic Test System; Guidance for Industry and FDA* document provided by CDRH/ FDA.

- **Conclusion**

  The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus the subject device is substantially equivalent to the predicate devices.